K071480

510(k) SUMMARY

SUBMITTED BY: C. Donald Kafader II
Director, Regulatory Affairs
DiaSorin Inc.
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082-0285
Phone (651) 351-5820
Fax (651) 351-5669
Email: **donald.kafader@diasorin.com**

OCT 1 " 2007

NAME OF DEVICE:

Trade Name: LIAISON® 25 OH Vitamin D TOTAL Assay,
LIAISON® 25 OH Vitamin D TOTAL Control Set
LIAISON® 25 OH Vitamin D TOTAL Specimen Diluent Set

Common Names/Descriptions: Vitamin D Test Reagents, Controls and Diluent

Classification Name: Vitamin D Test System (21 CFR 862.1825)

Product Code: MRG, JJX

PREDICATE DEVICES: LIAISON® 25 OH Vitamin D Assay and Controls (K032844)

INTENDED USE: The LIAISON® 25 OH Vitamin D TOTAL Assay uses chemiluminescent immunoassay (CLIA) technology for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites in human serum, EDTA-plasma or lithium heparin plasma to be used in the assessment of vitamin D sufficiency. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions in an adult population.

The LIAISON® 25 OH Vitamin D TOTAL Control Set is intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay.

The LIAISON® 25 OH Vitamin D TOTAL Specimen Diluent Set may be used to dilute specimens with values greater that 150 ng/mL by the LIAISON® 25 OH Vitamin D TOTAL Assay.

DEVICE DESCRIPTION:	The LIAISON® 25 OH Vitamin D Assay (Cat. No. 310600) is an in vitro diagnostic device consisting of reagents provided in individual compartments within a plastic container called the Reagent Integral which allows for the performance of 100 determinations. The LIAISON® 25 OH Vitamin D TOTAL Control Set (Cat. No. 310601) consists of two controls (2 vials each) provided in a separate box. The LIAISON® 25OH Vitamin D TOTAL Specimen Diluent Set (Cat. No. 310602) may be used to dilute specimens with values greater than 150 ng/mL.
PERFORMANCE DATA:	
Functional Sensitivity	4 ng/mL
Linearity	Linearity over the assay measuring range (4 – 150 ng/mL) was demonstrated by diluting several serum specimens pre CLIA EP6-A. The linear regression coefficient for all sample dilutions was 0.994 and ranged from 0.988 to 0.998.
Reproducibility/Precision	Results with serum samples showed repeatability (within-assay variability) from 2.9 to 5.5% CV over a range of mean values from 7.7 to 128 ng/mL and reproducibility (between-assay variability) from 6.3 to 12.9% CV. Results for plasma samples showed repeatability (within-assay variability) from 3.2 to 8.1% CV over a range of mean values from 5.9 to 62.7 ng/mL and reproducibility (between-assay variability) from 6.9 to 12.7% CV.
Method Comparison/(Correlation)	A method comparison study was conducted with a commercial radioimmunoassay product. The linear regression analysis demonstrated the following: LIAISON = 0.99(RIA) + 2.4, R=0.97
CONCLUSION:	The LIAISON 25 OH Vitamin D TOTAL Assay is substantially equivalent to the predicate assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DiaSorin, Inc
c/o Mr. Charles D. Kafader II
Director, Regulatory Affairs
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082

OCT 1 ˇ 2007

Re: k071480
Trade/Device Name: LIAISION® 25 OH Vitamin D Total Assay
LIAISION® 25 OH Vitamin D Total Control Set,
Specimen Diluent Set
Regulation Number: 21 CFR 862.1825
Regulation Name: Vitamin D Test System
Regulatory Class: Class II
Product Code: MRG, JJX
Dated: September 14, 2007
Received: September 25, 2007

Dear Mr. Kafader:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K071480

Device Name:

LIAISON® 25 OH Vitamin D TOTAL Assay
LIAISON® 25 OH Vitamin D TOTAL Control Set
LIAISON® 25 OH Vitamin D TOTAL Specimen Diluent Set

Indication For Use:

The LIAISON® 25 OH Vitamin D TOTAL Assay uses chemiluminescent immunoassay (CLIA) technology for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites in human serum, EDTA-plasma or lithium heparin plasma to be used in the assessment of vitamin D sufficiency. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions in an adult population.

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Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K071480